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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,410	01/25/2001	Christian Huber	P-576	6186

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EXAMINER

THERKORN, ERNEST G

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,410

Applicant(s)

HUBER ET AL.

Examiner

Ernest G. Therkorn

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-76, 79-81, 84-92, 95 and 97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-76, 79-81, 84-92, 95 and 97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 51-76, 79-81, 84-92, 95, and 97 are rejected under 35 U.S.C. 102(A) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gusev, Journal of Chromatography, 1999, pages 273-290. The claims are considered to read on Gusev, Journal of Chromatography, 1999, pages 273-290. However, if a difference exists between the claims and Gusev, Journal of Chromatography, 1999, pages 273-290, it would reside in optimizing the elements of Gusev, Journal of Chromatography, 1999, pages 273-290. It would have been obvious to optimize the elements of Gusev, Journal of Chromatography, 1999, pages 273-290 to enhance separation.

Claims 57-58 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gusev, Journal of Chromatography, 1999, pages 273-290 in view of Peters (U.S. Patent No. 5,929,214). At best, the claims differ from Gusev, Journal of Chromatography, 1999, pages 273-290 in reciting channels sufficiently large to allow convective flow. Peters (U.S. Patent No. 5,929,214) (column 2, lines 27-37) discloses

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that large channels that allow convective flow also allow high flow rates through a monolith. It would have been obvious to have sufficiently large channels to allow convective flow in Gusev, Journal of Chromatography, 1999, pages 273-290 because Peters (U.S. Patent No. 5,929,214) (column 2, lines 27-37) discloses that large channels that allow convective flow also allow high flow rates through a monolith.

Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gusev, Journal of Chromatography, 1999, pages 273-290 in view of Girot (U.S. Patent No. 6,045,697). At best, the claim differs from Gusev, Journal of Chromatography, 1999, pages 273-290 in reciting use of a tetrahydrofuran porogen. Girot (U.S. Patent No. 6,045,697) (column 16, lines 3-16) discloses that tetrahydrofuran is a suitable porogen. It would have been obvious to use tetrahydrofuran as a porogen in Gusev, Journal of Chromatography, 1999, pages 273-290 because Girot (U.S. Patent No. 6,045,697) (column 16, lines 3-16) discloses that tetrahydrofuran is a suitable porogen.

Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gusev, Journal of Chromatography, 1999, pages 273-290 in view of either Huber (Anal. Chem. 1998, 70, 5288-5295) or Griffey (Journal of Mass Spectrometry, Vol. 32, 305-313 1997). At best, the claim differs from Gusev, Journal of Chromatography, 1999, pages 273-290 in reciting use of a mass spectrometer. Huber (Anal. Chem. 1998, 70, 5288-5295) (page 5288, column 1) discloses electrospray mass spectrometry allows accurate molecular determinations in the picomole range. Griffey (Journal of Mass Spectrometry, Vol. 32, 305-313 1997) (page 305, column 2) discloses that electrospray mass spectrometry is a gentle sensitive method of analysis. It would have been obvious to

use mass spectrometry in Gusev, Journal of Chromatography, 1999, pages 273-290 either because Huber (Anal. Chem. 1998, 70, 5288-5295) (page 5288, column 1) discloses electrospray mass spectrometry allows accurate molecular determinations in the picomole range or because Griffey (Journal of Mass Spectrometry, Vol. 32, 305-313 1997) (page 305, column 2) discloses that electrospray mass spectrometry is a gentle sensitive method of analysis.

Claims 51-66, 71, 73-76, 79-81, 84-85, and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649), Huang (Journal of Chromatography 788 (1997) 155-164), and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457). At best, the claims differ from each of Frechet (U.S. Patent No. 5,344,310) and Hatch (U.S. Patent No. 6,238,565) in reciting use of a fused silica capillary, the clarity of covalent bonding, and a size of less than one millimeter in diameter. Frechet (U.S. Patent No. 5,344,310) itself (column 4, line 27) discloses a glass column. Peters (Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary. Huang (Journal of Chromatography 788 (1997) 155-164) (the paragraph bridging columns 1 and 2 on page 158) discloses that covalently bound vinyl groups offer anchoring sites for the polymer. Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) (pages 27-28) discloses that smaller diameter columns are the trend in chromatography because of improved concentration detection limits and the small amounts of sample available

for analysis. It would have been obvious to use a fused silica column in either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) because Peters (Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary. It would have been obvious that the polymer is covalently bound because Huang (Journal of Chromatography 788 (1997) 155-164) (the paragraph bridging columns 1 and 2 on page 158) discloses that covalently bound vinyl groups offer anchoring sites for the polymer. It would have been obvious to use a column less than 1 millimeter in diameter because Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) (pages 27-28) discloses that smaller diameter columns are the trend in chromatography because of improved concentration detection limits and the small amounts of sample available for analysis.

Claims 67-70 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649) and Huang (Journal of Chromatography 788 (1997) 155-164). At best, the claims differ from each of Frechet (U.S. Patent No. 5,344,310) and Hatch (U.S. Patent No. 6,238,565) in reciting use of a fused silica capillary and the clarity of covalent bonding. Frechet (U.S. Patent No. 5,344,310) itself (column 4, line 27) discloses a glass column. Peters (Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary. Huang (Journal of Chromatography 788 (1997) 155-164) (the

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paragraph bridging columns 1 and 2 on page 158) discloses that covalently bound vinyl groups offer anchoring sites for the polymer. It would have been obvious to use a fused silica column in either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) because Peters (Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary. It would have been obvious that the polymer is covalently bound because Huang (Journal of Chromatography 788 (1997) 155-164) (the paragraph bridging columns 1 and 2 on page 158) discloses that covalently bound vinyl groups offer anchoring sites for the polymer.

Claims 86-92 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649) and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457). At best, the claims differ from each of Frechet (U.S. Patent No. 5,344,310) and Hatch (U.S. Patent No. 6,238,565) in reciting use of a fused silica capillary and a size of less than one millimeter in diameter. Frechet (U.S. Patent No. 5,344,310) itself (column 4, line 27) discloses a glass column. Peters (Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary. Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) (pages 27-28) discloses that smaller diameter columns are the trend in chromatography because of improved concentration detection limits and the small amounts of sample

available for analysis. It would have been obvious to use a fused silica column in either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) because Peters (Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary. It would have been obvious to use a column less than 1 millimeter in diameter because Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) (pages 27-28) discloses that smaller diameter columns are the trend in chromatography because of improved concentration detection limits and the small amounts of sample available for analysis.

Claims 57-58 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649), Huang (Journal of Chromatography 788 (1997) 155-164), and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) as applied to claims 51-66, 71, 73-76, 79-81, 84-85, and 95 above, and further in view of Peters (U.S. Patent No. 5,929,214). At best, the claims differ from either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649), Huang (Journal of Chromatography 788 (1997) 155-164), and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) in reciting channels sufficiently large to allow convective flow. Peters (U.S. Patent No. 5,929,214) (column 2, lines 27-37) discloses that large channels that allow convective flow also allow high flow rates through a monolith. It would have been obvious to have sufficiently large channels to allow convective flow in either Frechet (U.S. Patent No. 5,344,310) or Hatch

(U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649), Huang (Journal of Chromatography 788 (1997) 155-164), and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) because Peters (U.S. Patent No. 5,929,214) (column 2, lines 27-37) discloses that large channels that allow convective flow also allow high flow rates through a monolith.

Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649) and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) as applied to claims 86-92 and 97 above, and further in view of Girot (U.S. Patent No. 6,045,697). At best, the claim differs from either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649) and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) in reciting a tetrahydrofuran porogen. Girot (U.S. Patent No. 6,045,697) (column 16, lines 3-16) discloses that tetrahydrofuran is a suitable porogen. It would have been obvious to use tetrahydrofuran as a porogen in either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649) and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) because Girot (U.S. Patent No. 6,045,697) (column 16, lines 3-16) discloses that tetrahydrofuran is a suitable porogen.

Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649), Huang (Journal of Chromatography 788

(1997) 155-164), and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) as applied to claims 51-66, 71, 73-76, 79-85, and 95 above, and further in view of either Huber (Anal. Chem. 1998, 70, 5288-5295) or Griffey (Journal of Mass Spectrometry, Vol. 32, 305-313 1997). At best, the claim differs from either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649), Huang (Journal of Chromatography 788 (1997) 155-164), and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) in reciting use of a mass spectrometer. Huber (Anal. Chem. 1998, 70, 5288-5295) (page 5288, column 1) discloses electrospray mass spectrometry allows accurate molecular determinations in the picomole range. Griffey (Journal of Mass Spectrometry, Vol. 32, 305-313 1997) (page 305, column 2) discloses that electrospray mass spectrometry is a gentle sensitive method of analysis. It would have been obvious to use mass spectrometry in either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) in view of Peters (Anal. Chem. 1997, 69, 3646-3649), Huang (Journal of Chromatography 788 (1997) 155-164), and Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) either because Huber (Anal. Chem. 1998, 70, 5288-5295) (page 5288, column 1) discloses electrospray mass spectrometry allows accurate molecular determinations in the picomole range or because Griffey (Journal of Mass Spectrometry, Vol. 32, 305-313 1997) (page 305, column 2) discloses that electrospray mass spectrometry is a gentle sensitive method of analysis.

The remarks urge that Gusev, Journal of Chromatography, 1999, pages 273-290 and Hatch (U.S. Patent No. 6,238,565) are not proper prior art references because the

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present invention was invented prior to the publication of Gusev, Journal of Chromatography, 1999, pages 273-290 and Hatch (U.S. Patent No. 6,238,565).

However, the 37 CFR 1.131 declaration fails to overcome Gusev, Journal of Chromatography, 1999, pages 273-290 as a reference. First, the declaration does not state that the work was done in the U.S., a NAFTA country, or a WTO country. Second, the evidence submitted is insufficient to establish applicants' alleged actual reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the references. For example, there appears to be no indication in the notebook that the monolith was in a fused silica tube having a diameter in the range or 1 to 1000 micrometers, the chromatographic surfaces were non-polar, or the matrix was underivatized. The hand written portions of the notebook appear to be either in a non-English language, illegible, or both.

The remarks urge patentability based upon using the column for DNA purification. However, the claims are directed to apparatus claims. As such, they are not considered to be limited to any particular use. Accordingly, the claims are not limited to DNA use.

The remarks urge patentability based upon the allegation that there is no motivation to combine either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) with Peters (Anal. Chem. 1997, 69, 3646-3649). However, Frechet (U.S. Patent No. 5,344,310) itself (column 4, line 27) discloses a glass column. Peters (Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical

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modification of the walls of the capillary. Accordingly, motivation exists to use a fused silica column in either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) because Peters (Anal. Chem. 1997, 69, 3646-3649) (page 3646 the Abstract and page 3649, column 2) discloses that use of a fused silica column eliminates the need for initial chemical modification of the walls of the capillary.

The remarks urge patentability based upon the allegation that there is no motivation to combine either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) with Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457). However, Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) (pages 27-28) discloses that smaller diameter columns are the trend in chromatography because of improved concentration detection limits and the small amounts of sample available for analysis. Accordingly, motivation exists to use a column less than 1 millimeter in diameter in either Frechet (U.S. Patent No. 5,344,310) or Hatch (U.S. Patent No. 6,238,565) because Tomer (Mass Spectrometry Reviews, 1994, 13, 431-457) (pages 27-28) discloses that smaller diameter columns are the trend in chromatography because of improved concentration detection limits and the small amounts of sample available for analysis.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

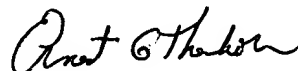
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to E. Therkorn at telephone number (571) 272-1149. The official fax number is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ernest G. Therkorn
Primary Examiner
Art Unit 1723

EGT
June 22, 2005